

U.S.S.N. 10/086,398

Filed: February 28, 2002

AMENDMENT AND RESPONSE TO OFFICE ACTION

Remarks

Claims 23-29 are pending. Claim 23 has been amended. Support for the amendment to claim 23 can be found, for example, at page 5, lines 17-26.

The present invention is directed to compositions for decreasing the production of A β comprising pharmaceutical formulations that are effective in the neuronal cells.

Rejection Under 35 U.S.C. § 102

Claims 23-29 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,866,090 to Hoffman *et al.* ("Hoffman"); U.S. Patent No. 5,350,758 to Wannamaker *et al.* ("Wannamaker"); and U.S. Patent No. 5,362,732 to Spielvogel *et al.* ("Spielvogel"). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

The claims, as presently amended, are directed to compositions that lower cholesterol, in an amount effective to decrease production of A β in neuronal cells. The pharmacological effects of the compounds cited in the prior (each of Hoffman, Spielvogel, and Wannamaker), are not described as being present in an amount that decreases production of A β in neuronal cells, nor is there any indication the drugs would even reach the brain or have any effect on production of A β in neuronal cells.

Moreover, the dosages that are effective in lowering cholesterol versus lowering the amount of amyloid precursor protein are different. The Examiner is respectfully directed to page 3, lines 11-13, which indicates one can see efficacy in the claimed treatment at dosages that would not be clinically efficacious in lowering cholesterol.

589751v1

*Ans
and
cleaned*

U.S.S.N. 10/086,398

Filed: February 28, 2002

AMENDMENT AND RESPONSE TO OFFICE ACTION

Accordingly, not only is the mechanism different, the dosage is different, and to the extent it is relevant, the patient population may be different. The prior art does not lead one to believe that lowering cholesterol would have any effect on treatment of Alzheimers. Therefore the claimed subject matter is novel.

Rejection Under 35 U.S.C. § 103

Claims 26 and 27 were rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,350,738 to Wannamaker *et al.* ("Wannamaker"). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

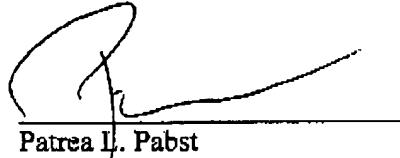
The Examiner has stated that one skilled in the art would be motivated to use the compounds of Wannamaker to cause the uptake (to decrease the uptake?) of dietary cholesterol since the reference teaches at column 16, lines 44-64, that the compounds can be within an oral form with an edible carrier. However, as discussed above, there is no art showing the connection between these compounds and a decrease in production of A β in neuronal cells, that one could treat individuals with a dosage effective in decreasing production of A β in neuronal cells which might not be effective in lowering cholesterol, or even that the drugs would reach and effect the neuronal cells.

U.S.S.N. 10/086,398
Filed: February 28, 2002
AMENDMENT AND RESPONSE TO OFFICE ACTION

Accordingly, the claims are not obvious over Wannamaker.

Allowance of claims 23-29 is respectfully solicited.

Respectfully submitted,



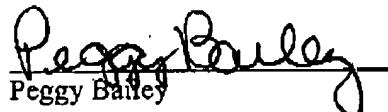
Patrea L. Pabst
Reg. No. 31,284

Date: September 11, 2003

HOLLAND & KNIGHT LLP
One Atlantic Center, Suite 2000
1201 West Peachtree Street
Atlanta, Georgia 30309-3400
(404) 817-8473
(404) 817-8588 (Fax)

Certificate of Facsimile Transmission

I hereby certify that this Amendment and Response to Office Action, and any documents referred to as attached therein are being facsimile transmitted on this date, October 11, 2003, to the Commissioner for Patents, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450.



Peggy Bailey

Date: September 11, 2003

ATL1 #589751 v1

589751v1

5

CMCC 654 DIV 2
078856/00059